IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Richard J. Lewis, *et al.*

Serial No.	09/787,986	Examiner:	Chih-Min Kam
Filed:	June 27, 2001	Art Unit:	1653
For:	NOVEL PEPTIDES	Docket:	14438

Commissioner for Patents
Alexandria, VA 22313-1450

DECLARATION OF RICHARD JAMES LEWIS UNDER 37 C.F.R. §1.132

Sir:

I, Richard James LEWIS, Australian citizen, do hereby declare:

1. I am an inventor of United States Patent Application No. 09/787,986 filed on 1 October 1999.

2. I completed a PhD on the isolation and pharmacology of ciguatoxins in Australian ciguateric fishes in 1985, and have continued research on ciguatera to the present.

3. I am now recognised as the leading international expert on ciguatera fish poisoning, with important contributions to the origin, chemistry, pharmacology and detection of ciguatoxins. Since 1995, I have expanded my research interests by initiating research into conotoxins at the Institute of Molecular Biology. Leading a multidisciplinary research team, I have contributed extensively to the discovery, structure and molecular pharmacology of conotoxins, especially those targeting transporters, GPCRs, and ligand-gated and voltage-sensitive ion channels.

4. I currently supervise six PhD students investigating the molecular pharmacology of conotoxins, focussing on conotoxins with potential analgaesic properties. I am a consultant to AMRAD in relation to the development of the ω-conotoxin, CVID. I have published over 123 papers to-date, including 96 peer-reviewed manuscripts and

over 20 review articles. I regularly publish in high impact journals including *Nature Neuroscience, Journal of Biological Chemistry, Journal of the American Chemical Society, Biochemistry, Journal of Molecular Biology, Journal of Medicinal Chemistry* and *Structure*. I have also contributed numerous published abstracts at national and international conferences.

5. Noradrenaline (norepinephrine) is well known in the art to produce an analgesic action in the spinal cord. The anti-allodynia effects in rats of intrathecally administered MrIA, a noradrenaline transporter inhibitor, provide further evidence of the analgesic effects of elevated levels of noradrenaline. MrIB is a closely related peptide to MrIA (differs by one residue) and has a similar ability (2-fold less potent) to enhance the contractile response of rat vas deferens, a simple *in vitro* measure of noradrenaline transporter inhibition. Thus, it is my opinion that MrIB is expected to produce a similar antiallodynic effect as MrIA, and thus be useful in the treatment of allodynia and related pain.

I further declare that all statements made herein on my own knowledge are true and that all statements are made on information that is believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Capital Title 18 of the United States code and that such wilful false statements may jeopardise the validity of the application or any patent issuing thereon.

DATED this 30th day of January, 2004

R. Lewis.

Richard James LEWIS